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IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

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PENNSYLVANIA EMPLOYEE BENEFIT	:	CIVIL ACTION
TRUST FUND, on behalf of itself	:	
and all others similarly	:	
situated,	:	
	:	
Plaintiff	:	
	:	
vs.	:	
	:	
ZENECA, INC; and ASTRAZENECA	:	
PHARMACEUTICALS, L.P.,	:	
	:	
Defendants	:	NO. 04-135 (SLR)

- - -

Wilmington, Delaware
Friday, September 9, 2005
10:00 o'clock, a.m.

- - -

BEFORE: HONORABLE SUE L. ROBINSON, Chief Judge

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APPEARANCES:

CHIMICLES & TIKELLIS LLP
BY: A. ZACHARY NAYLOR, ESQ.

-and-

SPECTOR, ROSEMAN & KODROFF, P.C.
BY: JEFFREY L. KODROFF, ESQ.

-and-

Valerie J. Gunning
Official Court Reporter

1 APPEARANCES (Continued)

2 ZIMMERMAN REED
BY: RONALD S. GOLDSER, ESQ.
(Minneapolis, Minnesota)

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5 Hagens Berman Sobol Shapiro LLP
BY: THOMAS M. SOBOL, ESQ.
(Cambridge, Massachusetts)

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8 MILLER FAUCHER AND CAFFERTY
BY: ELLEN MERIWETHER, ESQ.
(Philadelphia, Pennsylvania)

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11 GOODKIND LABAYON RUDOFF & SUCHANOW LLP
BY: CHRISTOPHER J. McDONALD, ESQ.
(New York, New York)

12 Counsel for Plaintiffs

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14 MORRIS, NICHOLS, AUSTY & TUNNELL
BY: JACK B. BLUMENFELD, ESQ.,
R. JUDSON SCAGGS, JR., ESQ. and
NATALIE HASKINS, ESQ.

15 -and-

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17 SIDLEY AUSTIN BROWN & WOOD LLP
BY: MARK E. HADDAD, ESQ.
(Los Angeles, California)

18 Counsel for Defendants

1 Benefit Trust Fund.

2 MR. McDONALD: Good morning, your Honor.

3 Christopher McDonald, on behalf of plaintiffs. In particular

4 Walters.

5 THE COURT: All right. Thank you very much.

6 MR. NAYLOR: Good morning, your Honor. Zachary

7 Naylor, Chimicles & Tikellis, liaison counsel for all

8 plaintiffs.

9 THE COURT: All right. Thank you.

10 MS. MERIWETHER: Good morning, your Honor.

11 Ellen Meriwether, from Miller Faucher and Cafferty, on behalf

12 of all plaintiffs, and particularly my client is Joe

13 Macklin.

14 THE COURT: All right. Thank you.

15 MR. HADDAD: Good morning, your Honor. I am

16 Mark Haddad, from Sidley Austin Brown & Wood, for the

17 defendants.

18 MR. BLUMENFELD: Good morning, your Honor. Nice

19 to be here again.

20 THE COURT: I'm sure.

21 MR. SCAGGS: Good morning, your Honor. R.J.

22 Scaggs.

23 MS. HASKINS: Good morning, your Honor. Natalie

24 Haskins, from Morris Nichols.

25 THE COURT: All right. Thank you very much,

1 PROCEEDINGS

2 (Proceedings commenced in the courtroom,

3 beginning at 10:00 a.m.)

4 THE COURT: Good morning.

5 (Counsel respond, "Good morning, your Honor.")

6 THE COURT: Mr. Blumenfeld, I feel like you live

7 here over the last few days. In any event, why don't we make

8 some introductions, and then it's defendants motion, so

9 defendant should proceed.

10 MR. SOBOL: Good morning, your Honor.

11 THE COURT: Good morning.

12 MR. SOBOL: My name is Tom Sobol. I'm with

13 Hagens Berman Sobol Shapiro, for the plaintiffs.

14 MR. HADDAD: Good morning, your Honor. Go

15 ahead.

16 MR. GOLDSER: Good morning, your Honor. Ron

17 Goldser. I'm from the Zimmerman Reed firm in Minneapolis,

18 also for plaintiffs, and my client in particular is Linda

19 Walters.

20 THE COURT: Thank you.

21 MR. KODROFF: Good morning, your Honor. Jeffrey

22 Kodross, Spector, Roseman & Kodroff, Pennsylvania Employees

1 counsel.

2 Why don't we have defendants' counsel begin on

3 their motion.

4 MR. HADDAD: Thank you very much, your Honor.

5 What I'd like to do this morning, if I may, is

6 spend just a few brief moments on the injury and causation

7 issues and then spend the bulk of my time on the preemption

8 issues.

9 With respect to injury and causation, AstraZeneca

10 has a straightforward submission here. We say that at a

11 minimum to plead a valid complaint, plaintiffs have to plead

12 the elements of the economic loss claim that they are

13 bringing. And for each of the plaintiffs, they failed to

14 plead the rudiments of either economic injury and loss or a

15 causal link between such loss and the conduct they are

16 complaining about.

17 With respect to the individuals, this is

18 particularly stark. We have four individual plaintiffs, one

19 of whom alleges that he purchased Nexium for his personal use

20 and the other three who allege that they paid co-payments for

21 Nexium. That is where the allegations begin and that is

22 where they end.

23 There is no further allegation about what they

24 would have purchased or been prescribed by their physician if

25 they hadn't been prescribed Nexium. There's no allegation of

1 what they would have paid for whatever this other medication
2 would have been if it had not been Nexium. And this is
3 just a stark example of no -- only giving you one-half of
4 the equation, if you will. We know that they paid something,
5 but we don't know what they would have paid in the
6 alternative.

7 With respect to the causation element, we don't
8 know in particular whether there is any relationship between
9 the advertising and the prescription that each of these
10 individual plaintiffs received. We don't know what each of
11 these plaintiff's physicians would have done but for the
12 conduct that is being challenged here.

13 There are a number of other PTIs in the
14 marketplace. Which one would these plaintiffs have
15 gotten? They don't allege what their physicians would have
16 done but for the ads. They don't allege that their
17 physicians were misled by the ads. They don't allege that
18 their physicians saw the ads. For that matter, they don't
19 allege that they themselves saw the ads.

20 So there is a complete disconnect, in other
21 words, in the complaint between the experiences of these four
22 plaintiffs, individual plaintiffs, and the conduct that they
23 are complaining about.

24 Plaintiffs have attempted to overcome this by
25 generic allegations at the back of their complaint that

1 made for Nexium.

2 There's no allegation that anybody at the
3 third-party payers saw any of these ads, made a decision
4 based on these ads, or that the physicians, again, that
5 prescribed the Nexium to the beneficiaries to the third-party
6 payers relied on these ads.

7 So, again, we're not saying that they couldn't
8 make allegations that would satisfy the elements. We're just
9 saying that they have not and that they need to for the Court
10 to know and for us to know whether they have plaintiffs that
11 can establish standing under Article 3.

12 We think that the case that is closest to
13 this one on these issues is the New Jersey Citizen Action
14 Case versus Schering-Plough. That's a case that we've cited
15 in our papers. It's a case in which a very similar group of
16 individuals and public interest organizations sued the
17 manufacture of Claritin, saying that the ads for Claritin
18 overstated the benefits of Claritin, made it seem as if, you
19 know, the world would be a much better place for all of these
20 patients if they would just take Claritin, and the theory
21 of the complaint was it wildly overstates the benefits, and
22 there are all these people in America who shouldn't be taking
23 Claritin and who are overpaying for it.

24 And the Court just said, Look, without
25 allegations of causation, even though in New Jersey,

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1 hundreds of thousands of people have been misled and so
2 forth, but we submit that what happened allegedly to hundreds
3 of thousands of individuals has no bearing and does not
4 tell us anything about what happened to these four
5 plaintiffs. We need to know what their factual allegations
6 are of their personal injury and their causal link to the
7 conduct before we know whether they have alleged facts that,
8 if they can prove them, would establish the elements of these
9 claims.

10 So it's a pleading issue that we think
11 is a threshold and significant issue for the individuals.
12 A fortiori plaintiffs, and there are three of those, there is
13 no injury or causation pleaded. The associations have
14 alleged no injury of any kind to themselves. They purport to
15 plead the case of their individual members, but they cannot
16 seek damages for their individual members and they have not
17 attempted to make the kind of elementary pleadings of
18 economic loss and causation for their individual members that
19 would allow them to seek injunctive relief, which is the most
20 they could conceivably seek.

21 That leaves just the three third-party payers.
22 And, again, the complaint is just empty of any factual
23 allegations that would either establish a concrete claim
24 of economic loss or that would link the ads to the
25 reimbursement that these third-party payers allege they

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1 for example, as in Delaware, there's no element of reliance
2 that's required under the Fraud Act, there is an element of
3 causation. And the Court dismissed the claim on the
4 pleadings in part because there were simply no allegations
5 that could meet the causation requirement.

6 So those are our essential positions with respect
7 to injury and causation.

8 We think that they require, at a minimum,
9 that the Court dismiss the complaint and understand that,
10 typically, an opportunity would be given to replead, although
11 we have to note that these plaintiffs have pleaded their case
12 in some instances more than once.

13 But I think the more fundamental question that I
14 wanted to spend a little bit more time on this morning is, Is
15 there a viable complaint here at all on the merits? Can
16 these plaintiffs litigate the essential claim that they want
17 to bring?

18 And here, your Honor, we submit that they
19 cannot. We submit that there is a huge problem on the merits
20 of their case that prevents them from going forward with the
21 case that they want to bring and that they cannot plead
22 around. And the huge problem is that what they want to
23 challenge is really not advertising, it's agency action.
24 It's a decision by the Food & Drug Administration to
25 approve Nexium as a new drug and to approve in particular

1 a 40-milligram dose of Nexium for the healing of erosive
2 esophagitis.

3 The significance of that is this: By
4 approving a 40-milligram dose of Nexium for healing
5 erosive esophagitis, the FDA relied upon and necessarily
6 found that the studies that plaintiffs want to say are
7 skewed and slanted in their words are, in fact, adequate
8 and well-controlled studies to the point that the FDA
9 approved summaries of these studies on the label that
10 appears necessarily by law covers every prescription of
11 Nexium, and the FDA approved in particular the 40-milligram
12 dose in comparison to both 20-milligram doses of Nexium and
13 20-milligram doses of Prilosec, 20 milligrams of Prilosec
14 being the maximum recommended dose for the same indication of
15 healing erosive esophagitis.

16 And when one looks at the labeling of Prilosec,
17 one sees that not only is 20 milligrams the maximum dose of
18 Prilosec, but the FDA declined to recommend a 40-milligram
19 dose of Prilosec.

20 So what plaintiffs want to argue is a, in their
21 words, a game, quote unquote, being played on American
22 consumers is, in fact, the product of an exhaustive,
23 deliberative agency process committed to the Federal Food &
24 Drug Administration by Congress to, in effect, to, in fact,
25 approve these different dosages with their different levels

And if you turn to Tab No. 2, which is on Page
2 of the labeling, you see the discussion of the studies that
3 support the dosage for erosive esophagitis, and there you
4 find a summary of the study that the FDA concluded did not
5 show that 40 milligrams of Prilosec was more effective than
6 20 milligrams, and therefore led the FDA not to approve a
7 dosage of 40 milligrams of Prilosec.

8 Now, the stark comparison and really the core
9 of the case is when you look at the Nexium labeling, which
10 is Exhibit 1, and, in particular, look at Tab 3, if you
11 would.

12 Tab 3 has the corresponding recommended adult
13 dosage for Nexium, and the Court will see that the FDA
14 approved both 20 and 40 milligrams of Nexium for the same
15 indication of the healing of erosive esophagitis.

16 And turning, then, to Tab 4, which begins at
17 Page 13, here we have the clinical studies on which the
18 approved doses were based. And these studies show to the
19 FDA's satisfaction that it is appropriate to approve and to
20 prescribe a 40-milligram dose of Nexium for the healing of
21 erosive esophagitis.

22 And, in particular, it is Studies No. 2 and No. 4
23 which are summarized here that show a significant difference
24 in the effectiveness of Nexium as opposed to Omeprazole,
25 which is the generic name for Prilosec.

1 of effectiveness of these two drugs?

2 To see how stark this is, I would like, if I may,
3 to hand up to the Court a copy of our request for judicial
4 notice, which is unopposed and which contains the two
5 critical labels here for our argument, the Prilosec and
6 Nexium label.

7 THE COURT: All right.

8 (Mr. Haddad handed documents to the Court.)

9 MR. HADDAD: Your Honor, I have, to facilitate
10 matters, I have put numbered tabs on the copies.

11 THE COURT: All right. And I might hand back
12 the second copy you gave me, but I will do that later.

13 MR. HADDAD: Okay. I didn't know if a law clerk
14 or someone would want that.

15 The second of the two exhibits in our request for
16 judicial notice is the Prilosec label. And what you will see
17 tabbed as Tab 1 is Page 24 of the Prilosec label. And that
18 is the part of the Prilosec labeling that refers to the
19 dosage and administration that the FDA approves for each of
20 the different indications. And highlighted at the bottom of
21 Page 24 is the recommended adult oral dose for the treatment
22 of patients with symptomatic GERD, and then continuing on 25,
23 the recommended dose for patients with erosive esophagitis
24 due to GERD. And in each case, that dose is 20 milligrams
25 per day.

1 Study 2, for example, showed that at Week 4, the
2 percentage of patients that were healed on a regimen of
3 Nexium and 40 milligrams was 75.9 percent whereas only 64.7
4 percent of the patients who were taking Prilosec at 20
5 milligrams were similarly healed.

6 And your Honor can look at the similar
7 comparisons for Week 8 for Study 2 and, of course, for Study
8 No. 4 with that same comparison of the maximum approved dose
9 of Nexium at 40 and the maximum approved dose of Omeprazole
10 at 20.

11 Now, this table compared the studies that looked
12 at the healing of the condition of erosive esophagitis of the
13 erosions in the esophagus. Table 2 measured a different
14 aspect. This is how long it took to get to what the studies
15 defined as the sustained resolution of heartburn symptoms.
16 And, again, Studies 2 and 4 showed that Nexium was
17 significantly more effective than, at its maximum dose of 40
18 milligrams than was Omeprazole or Prilosec.

19 So what plaintiffs want to call a game is, in
20 fact, the FDA's decision to recognize that Nexium at 40
21 milligrams is more effective at healing erosions in the
22 esophagus and at producing sustained resolution of heartburn
23 symptoms for patients with erosive esophagitis than Prilosec
24 at its maximum dose of 20 milligrams.

25 And our fundamental position is that if

1 plaintiffs want to bring a lawsuit challenging the so-called
2 game about skewed studies or dosages, that is a complaint
3 they have to bring to the FDA or to Congress, but not to a
4 federal or state court.

5 Now, I think it would be helpful to look at the
6 implications for the particular allegations and claims that
7 plaintiffs have made about the ads here because I think with
8 this basis in the record, I think we can see that the ads
9 that they are attempting to challenge are all variations on a
10 theme that is trying to attack agency action.

11 Our fundamental position, and I don't think
12 plaintiffs -- plaintiffs certainly have not contested this.
13 Whether they would say they concede it, I don't know, but
14 they seem to accept the framework that I'm about to propose
15 at Pages 1 to 2 and 25 of their opposition.

16 But, in any event, we think the basic framework
17 is plain. You have to look at the ads they are challenging
18 in light of the labeling that the FDA has approved. The
19 labeling creates a basic federally approved framework for the
20 types of statements that a manufacturer can make about a
21 prescription drug.

22 Now, if the manufacturer goes outside the label,
23 makes claims that aren't supported by the label, then state
24 law can provide a remedy. If a manufacturer omits an
25 important warning that relates to health and safety, Courts

1 milligrams over the counter was the same as 150. The
2 manufacturer could not recommend or suggest that two doses of
3 Zantac 75 were the same. That was not permitted under
4 federal law.

5 So the omission that was the heart of the Bober
6 case simply wasn't within the realm of what the company could
7 do under the federal framework. They were complying with the
8 federal framework by separately advertising their products
9 and, therefore, there was no liability, no case could go
10 forward.

11 The same is true here. I think we have a more
12 compelling case, frankly, than Bober. Here, the critical
13 omission that they allege throughout to attack all of the ads
14 is an alleged failure on AstraZeneca's part to say that
15 the "exact same relief" is available with Prilosec.

16 And omission theory is critical to their case,
17 by the way, because they want to attack the entire
18 direct-to-consumer advertising campaign. They want to say
19 that AstraZeneca built up an entire market for its product
20 with every ad and so the critical way they want to do that is
21 through an omission theory. Every ad failed to say that
22 there's another AstraZeneca product that's exactly the same,
23 provides the exact same relief, that's just as good, et
24 cetera.

25 Now, that is not something under federal law that

1 have held that that kind of claim isn't preempted. But
2 that's not what we have here. We have advertising statements
3 that are supported by and are consistent with the labeling,
4 and in those situations, there is no cause of action. There
5 is certainly no cause of action under Delaware law because
6 Delaware law, the Delaware Consumer Fraud Act, expressly
7 creates a safe harbor and accepts advertising that complies
8 with federal law as administered by the FTC.

9 And that's, I think, Section 2513(b) of the
10 Delaware Consumer Fraud Act. And the case that is most on
11 point here is the Seventh Circuit's decision in Bober,
12 B-o-b-e-r. Bober is another double-dose case that was
13 dismissed on the pleadings and affirmed by the Seventh
14 Circuit. And there as here, the essential claim was that the
15 manufacturer was misleading the plaintiff and the class that
16 was alleged, thereby failing to tell them that they could
17 take two doses of the over the counter product Zantac,
18 75 milligrams, and get the same benefit as if they took the
19 more expensive single prescription dose of 150 milligrams of
20 Zantac.

21 And the Seventh Circuit affirmed the dismissal of
22 that case on the pleadings. The Court noted that 75
23 milligrams of Zantac over the counter was a different drug
24 under federal regulation than 150 milligrams of Zantac
25 prescription. There had been no studies to show whether 75

1 the FDA would permit AstraZeneca to say. It can't be said
2 even on the allegations of this complaint.

3 The plaintiffs acknowledge, and they have to,
4 that on the labeling as shown, there is a difference between
5 the recommended dose of Nexium at 40 milligrams and the
6 maximum recommended dose of Prilosec at 20 milligrams. There
7 is a clear difference shown on the labeling, supporting the
8 different dosages, in terms of the effectiveness of Nexium at
9 40 milligrams, at healing and relieving the symptoms of
10 erosive esophagitis.

11 And if you look at Paragraph 77 of the complaint,
12 you will see plaintiffs' fundamental answer to this problem.
13 They say, Well, the logical conclusion to draw from all of
14 these studies is you should have, AstraZeneca should have
15 doubled the dose of Prilosec and forgotten all about the new
16 purple pill, Nexium.

17 Well, it's an interesting argument, but it does
18 not support an advertising campaign. There is no approved
19 double dose of Prilosec. That has not been approved by the
20 FDA. There is no study showing that a double dose of
21 Prilosec is the same as Nexium.

22 AstraZeneca would violate its obligations as the
23 FDA has set them forth if it were to argue or even suggest or
24 recommend in its ads that patients take a double dose of
25 Prilosec. And we have cited the statutory, regulatory

1 authority and examples of the warning letters that are
2 publicly available on the FDA's website that are the
3 precursors to enforcement action that routinely occur when
4 companies try to recommend an unapproved dose.

5 So this omission theory just has no legal
6 foundation. It does not state a claim under Delaware law,
7 and even if there were Delaware or other state law that would
8 allow a claim like this to go forward, it would be preempted
9 under basic conflict preemption principles because state law
10 cannot require a disclosure that federal law prohibits.

11 Once we put this omission theory to one side,
12 there's very little left of their complaint. I think,
13 broadly speaking, we can look at two categories of claims
14 they want to make and try to make.

15 They -- the first category would be
16 misstatements. They have pointed to certain factual
17 statements in some of these ads. They've pointed to, for
18 example, the statement that Nexium is the number one PPI
19 recommended by gastroenterologists or that more patients have
20 been switched to Nexium than to any other PPI.

21 Well, those are factual statements, but what's
22 very significant about those statements is plaintiffs do not
23 allege that they are false. They do not allege that Nexium
24 is not or was not the number one PPI recommended by
25 gastroenterologists at the time the statement was made. They

1 court of law to see if it was true. But that's not what's
2 here in the ads.

3 As the Court goes through the ads, the Court
4 will see, there's not a single comparative statement overtly
5 of that nature at all. It's all implications. It's all
6 lurking between the lines, allegedly what someone would draw
7 from these factual statements that they cannot and do not
8 contest were false. And so our position is we are permitted
9 to make those factual statements because they are consistent
10 with the label, and by necessity any implications that arise
11 from statements that are consistent with the label are -- are
12 there in both the labeling and in the ads.

13 I expect that the plaintiffs may want to point to
14 certain ads, and if they do, we can look at whichever
15 particular ads they wish to highlight this morning and
16 perhaps in response I can look at those.

17 But I think if the Court looks just at one
18 example, it would be Paragraph 130 of the complaint, the
19 Court will see an example of just how lacking in substance
20 the claims of misleading ads are.

21 The upshot of all of this, your Honor, is this:
22 Plaintiffs want to embark on a very profound lawsuit. They
23 want to take up the challenge essentially to the entire
24 practice of direct-to-consumer advertising of this new
25 product.

1 don't claim that they can prove that more patients were
2 switched to some other PPI than to Nexium.

3 They just claim that statements like this create
4 by implication an aura that somehow Nexium is better than
5 Prilosec, and they think that that sort of aura or
6 implication is misleading.

7 Our position is that the same implication
8 necessarily would follow from the labeling. If AstraZeneca,
9 for example, republished the excerpt of the labeling that we
10 looked at in Exhibit 1 to the request for judicial notice,
11 the Nexium labeling a moment ago, plaintiffs would contend
12 that that also carries with it an implication that Nexium is
13 better than Prilosec. They have said in their complaint,
14 they have alleged that by doing the studies in the way
15 AstraZeneca did, we skewed and slanted those studies to
16 create a misleading implication of superiority.

17 The very same implication of superiority
18 that plaintiffs claim to be able to find in the ads
19 they challenge is right there on the label by the very
20 terms of the their own complaint. It's not, by the way,
21 to say that we are arguing that there could never be a
22 claim of superiority outside the labeling if there were
23 comparative statements that Nexium is -- works 50 times
24 faster than Prilosec. That's not on the labeling and
25 that's a factual assertion and that could be tested in a

1 In their view, as they allege it in the
2 complaint, Nexium should never have been brought on the
3 market. It was a mistake for the FDA to approve it, a
4 mistake for AstraZeneca to seek approval for it. In their
5 view, the studies, if properly done, would have shown no
6 benefit to Nexium. In their view, the studies properly
7 understood today show no benefit, and in their view, this is
8 a product that cannot be advertised unless it's accompanied
9 by disclaimers that say other products including our own are
10 just as good and cheaper.

11 That is not a valid basis for attacking
12 commercial speech. It's not a valid basis for attacking a
13 prescription drug because it changes, in effect, the
14 standards that Congress and the FDA have set for the approval
15 of new drugs. And, frankly, it trenches on basic commercial
16 speech protections. There's no obligation to advertise about
17 other drugs. If what you say about the drug that you
18 manufacture is fair and within the labeling, then your ad is
19 permissible. And if someone else wants to talk about other
20 drugs, other dosages, the marketplace is open to them.

21 The state has ways of communicating. Congress
22 and the FDA are available for policy debates about the
23 standards on which drugs should be approved. But state
24 unfair competition laws and common law do not exist to stifle
25 that speech.

1 Thank you.

2 THE COURT: Thank you very much.

3 MR. HADDAD: Thank you, your Honor.

4 MR. SOBOL: Good morning, your Honor.

5 THE COURT: Good morning.

6 MR. SOBOL: May it please the Court, Tom Sobol
7 for plaintiffs, your Honor. It's a pleasure to be here and
8 thank you for the Court's patience and time.

9 I think it's important for me to start at the
10 outset, your Honor, by putting a more accurate framework on
11 the allegations of the complaint that is before you because,
12 with all due respect to Mr. Haddad, there seems to be a
13 really fundamental misunderstanding about some of the core
14 allegations of the complaint as they really differ from some
15 of the statements that have been made.

16 So I would just -- just for a couple of moments
17 put that in the right framework.

18 Of course, a very simple procedural context in
19 12(b)(6), the allegations of the complaint control, and I
20 will also deal with some of the specific issues of the
21 regulations and the approval labeling Mr. Haddad has pointed
22 to.

23 But this case arises when AstraZeneca saw
24 the likelihood obviously of generic entry for its brand
25 name Prilosec and was trying to do and explore,

1 understandably, legitimate business objectives to try to
2 figure out a way to either continue on with the brand-name
3 position coming in with some alternative product. As a
4 result, among the things that it did, it explored the
5 possibility of trying to come up with a better drug.
6 Eventually that would be called Nexium.

7 They explored that through scientific effort.
8 Then they explored it through clinical studies. And when
9 they went through those studies, then they sought approval
10 for the drug, too.

11 AstraZeneca's effort before the FDA was in large
12 part to seek to have the FDA approve Nexium as better than
13 Prilosec. And the allegations of the complaint state that
14 there were 11 studies that were before the FDA. Only four of
15 them were comparative studies. Seven of them were basically
16 seeking to get Nexium approved as better than a placebo,
17 i.e., as better than nothing.

18 The allegations of the complaint control and also
19 through quotes from the FDA itself, the FDA approved Nexium
20 because it was better than a placebo. It was better than
21 nothing. And that is the only basis upon which the FDA
22 approved Nexium to be able to be marketed, sold, for
23 esophagitis and for GERD.

24 Now, in the context of that iterative process
25 between AstraZeneca and the FDA, AstraZeneca was trying to

2 than a placebo. The sponsor sought to get the FDA to agree
3 with them, the sponsor being AstraZeneca, of course, that
4 Nexium was better than Prilosec, and submitted to the FDA the
5 same studies that Mr. Haddad and other information that I can
6 identify for you today. There was other information also
7 behind -- before the FDA at that time.

8 The FDA did undertake a very exhaustive, thorough
9 process, and refused, unequivocally, and on multiple
10 occasions, to agree with the sponsor's request that it be
11 able to make representations that Nexium was better than
12 Prilosec. It failed in the fundamental mission of what they
13 were trying to do with this product.

14 The allegations of the complaint, then, cite on
15 various occasions -- I have a hand out here, if I may, your
16 Honor.

17 May I approach?

18 THE COURT: Yes.

19 (Mr. Sobol handed documents to the Court.)

20 MR. SOBOL: If, your Honor, you could turn to
21 Page 7 of the handout, these are allegations in the
22 complaint, but we're also referring to aspects of the FDA's
23 thorough and deliberative process when they rejected
24 AstraZeneca's effort as sponsor for Nexium to seek to get a
25 superiority claim for Nexium.

1 Paragraph 65. A superiority claim of Nexium over
2 Omeprazole, that's the generic Prilosec, is not supported by
3 either the comparison to the 20 milligram or to the 40
4 milligram. I'm obviously paraphrasing here.

5 Elsewhere in the complaint, your Honor, regarding
6 the treatment of symptomatic GERD, claims of superiority of
7 Nexium to the Omeprazole are, once again, not supported.
8 Neither the 20, nor the 40 milligram dosages, are
9 differentiated from the 20 of Prilosec.

10 There's another example, your Honor, Paragraph 68
11 of the complaint, where it's talking about a summary of the
12 benefits and risks of Nexium. Go down toward the bottom of
13 the bolded. Therefore, the sponsors, that's AstraZeneca's,
14 conclusions that Nexium has been shown to provide a
15 significant clinical advance over Prilosec in the first-line
16 treatment of patients with acid-related disorders is not
17 supported by the data.

18 If you go to the next page, your Honor, on
19 Page 8, I'm going to jump through Paragraph 69 to shorten
20 things up and go to Paragraph 76 of the complaint. The FDA
21 found there are no studies, not some, unequivocally, there
22 are no studies which demonstrate that Nexium is superior to
23 Prilosec clinically or even statistically.

24 In the 12(b)(6) context, your Honor, those
25 allegations control, and we also think we will be able to

1 approve beyond any doubt over time that AstraZeneca's
2 fundamental mission in terms of trying to come up with a
3 product that it could legitimately differentiate as better
4 than Prilosec have failed and that the FDA has rejected that
5 claim of superiority.

6 Now, if one, then, turns to the labels that
7 Mr. Haddad has pointed to, it is true that there is an
8 approved indication. The approved indication for Nexium is
9 simply that it is to be given, you know, for GERD and for
10 healing esophagitis. There is no -- nowhere in the label is
11 there any statement that it is being approved as better than
12 Prilosec at all, nowhere there. And, indeed, that would be
13 bizarre to be there because the FDA specifically rejected
14 that effort by AstraZeneca.

15 The FDA, in its labeling, can permit a sponsor,
16 when they are drafting the label, as a sponsor drafts the
17 label and submits it to the FDA, the FDA reviews it, it is
18 optional, if you go to Mr. Haddad's Tab 4, if one wishes on a
19 topic, and I think the regulations say it may be on a
20 nonessential, but it may be an important, you know, topic.
21 One can put in clinical studies to provide information to
22 clinicians.

23 Now, here, what the label does is simply provide
24 some of the raw data. In other words, these -- this
25 statement of clinical studies, there is nowhere on these two

1 studies showed that there was no significance. Two others
2 have a reasonable P value, but the increases weren't
3 significant.

4 And if you go to the next one, where you're
5 actually talking about the changes of the symptoms,
6 most of the studies came up with no difference at all and
7 where there are reasonable P values, there are very small
8 differences.

9 So the bottom line point is, including some
10 data so that practitioners out there in the world can see
11 some of the information and draw some conclusions that they
12 may or may not want to be able to draw on their own does not
13 really have to accept AstraZeneca's interpretation right now
14 on the pleadings. It's not as if we have done this in a
15 cursory way.

16 I think the complaint goes on in some detail as
17 well as our memorandum that we're drawing on unequivocal
18 statements by the FDA. We're not being cute about it. We're
19 not trying to pull something out of somewhere. We don't have
20 our own expert's opinion about this. We're not trying to
21 have a battle of experts here. We're going precisely to what
22 the FDA has projected that AstraZeneca could do.

23 And that, then, places in context a response to
24 most of the balance of the argument in terms of preemption
25 because, then going back to placing the case in context,

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1 pages or anywhere else of what the FDA's conclusion is about
2 the data or analysis of the data. There's no discussion
3 about it at all. And, indeed, if one goes back into the FDA
4 proceedings and the efforts by the sponsor repeatedly to try
5 to get the FDA to give them the superiority claim that the
6 FDA rejected, this is precisely some, not all of the data
7 that the FDA rejected as affording AstraZeneca an ability
8 to have a superiority claim of Nexium over Prilosec.

9 Indeed, so to say, this is raw data. In
10 other words, your Honor, this data on Page 13 and then
11 Page 14, this does not speak for itself. It requires
12 analysis against this data and the other body of
13 information itself.

14 One does not have to accept AstraZeneca's
15 interpretation now of this data, and that's what AstraZeneca
16 proposes that we do. In other words, it proposes that this
17 Court come up with the only conceivable interpretation that
18 they think is capable from this data in a 12(b)(6) motion
19 even though the record that the Court must assume, you know,
20 is accurate and which AstraZeneca hasn't disputed that the
21 FDA rejected this interpretation. In fact, concludes the
22 opposite.

23 Also, I would say, although I'm a layperson, in
24 looking at this, that the endoscopic analysis, that's the
25 first, when you go in, you take a peak. Actually, two of the

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1 AstraZeneca, once it got this formal approval by the FDA, but
2 the rejection of the claim of superiority, had on its hands a
3 product that was no better than the brand name product that
4 was going into generic competition, and it had choices it
5 could do.

6 Now, it didn't have the ability to differentiate
7 that product as better than Prilosec because that wouldn't be
8 true, and it would be beyond the label of what it is that had
9 been approved by the FDA.

10 Now, they are businesspeople. They could have
11 made a variety of decisions. They could have said, Well,
12 we'll compete on price. We'll put Nexium out and try
13 to differentiate on the difference of price. They could
14 have put it out and tried to differentiate that from some
15 other different kind of compound. But they did not do
16 those things. They could have said, You know what? This
17 R&D effort failed and it's not worth our effort to go
18 into the market with this additional drug because for us
19 to do that, you know, we don't have a legitimate basis to
20 differentiate.

21 But it chose something else. It chose, despite
22 the scientific evidence, despite the statements from the FDA
23 saying it's not any better, to go to market anyway,
24 pretending like it's a better drug. And that's what this
25 case is about. What this case is about is that this company

1 was not going to be stopped by what the evidence showed, and
 2 the science showed or what the FDA told them. They were
 3 going to go off and do it anyway and they did.

4 They went off, and I will get to this later about
 5 what our allegations show, but they engaged in a broad based,
 6 not only just ads, not just direct-to-consumer advertising,
 7 but also marshaling an Army of 6,000 sales representatives to
 8 go out there and flood doctors' offices with claims of a
 9 superiority of Nexium over Prilosec. And they did that
 10 contrary to what had occurred before, and that's the overall
 11 context of the case. And those what the allegations are,
 12 too.

13 Also, I would say, your Honor, these are not just
 14 plaintiffs' comments in terms of playing games. Obviously,
 15 we quoted a senior official in the Federal Government, Mr.
 16 Scully, who had two years into or so of the Nexium marketing
 17 effort, himself said this is a game. It's ridiculous. It's
 18 being played on you. It's the same drug. It's no better.
 19 They're charging more for it. It's a game.

20 These are not things that we've come up with on
 21 our own.

22 With those allegations, I would then turn to the
 23 preemption argument because, and there have been -- I think
 24 it's always a coupled process. When we have opening brief,
 25 opposition, reply brief and we have argument, the preemption

2 out there. In fact, what it shows is that your fundamental
 3 thing that you are trying to pursue is just wrong.

4 So they had many other choices other than to
 5 try to have some kind of forced speech or having to say
 6 something about, you know, double-dosing Prilosec or taking
 7 it twice. This is not a double dose case at all. We don't
 8 allege it that way. We don't say it that way. It's not what
 9 this is.

10 This case instead is a situation where they're
 11 going out and making affirmative statements or omitting to
 12 say things that are directly contrary to what they just have
 13 failed to get from the FDA.

14 The requirements of conflict preemption are
 15 obviously in the briefs, that kind of thing, but conflict
 16 preemption is probably the most difficult type of preemption
 17 to have. You have to show a very stark, bold requirement
 18 that the case to go forward would require you to do something
 19 directly contrary to what an FDA regulation or, you know,
 20 federal act would be. That's not what this case is about
 21 at all.

22 When the FDA approves Nexium is better than
 23 placebo, then no one is stopping them from going to market.
 24 They can market their drug. They can sell their drug but
 25 they can't be making comparative claims to Prilosec. And,

1 issue, although there's a lot of paper written on it before
 2 your Honor, really boils down to one thing. How that boiling
 3 happens is this. We now hear, there's obviously no express
 4 preemption argument then being made, some express argument.
 5 There's no field preemption argument being made. There is no
 6 other argument being made other than this somehow conflicts
 7 with what the FDA has already approved, and that's wrong for
 8 two fundamental reasons.

9 First, the FDA rejected this claim. They did not
 10 approve this claim. They rejected this claim. And so there
 11 can't be any conflict.

12 The second thing is that their argument, which
 13 ends up being somewhat of, at least for me a brain twister,
 14 is that, Well, your case, plaintiffs, boils down to
 15 things that we should have said, you know, that we omitted
 16 in saying, and that, therefore, there are other things
 17 you plaintiffs are telling us that we should have been
 18 saying.

19 That's not -- that's not the argument at all.
 20 We're not saying that they should have been in the market
 21 saying take Prilosec two times a day or take double dosage of
 22 Prilosec. That is not the case at all.

23 What we are saying is, don't go into the market
 24 and be making comparative claims to Prilosec to begin with.
 25 If you make comparative claims, the only way those things end

1 sure, that's going to be limiting, because that's the nature
 2 of the product that you have.

3 And when it comes to drugs, you can't
 4 differentiate your products by, you know, delivery systems or
 5 service, that kind of thing. It really ends up having to be
 6 the attributes of the drug itself, and they have failed to do
 7 that.

8 So preemption ultimately does not apply because
 9 there cannot be a conflict in an FDA determination that runs
 10 directly contrary to what they are trying to do. It's just
 11 they -- I would be repetitive on that.

12 Here, then, given the allegations of the
 13 complaint, as Mr. Haddad indicated, if the ads go beyond,
 14 if the direct-to-consumer advertising goes beyond, if the
 15 detailing and promotional efforts through the 6,000 people
 16 that are out there in the country go beyond the label, and
 17 they are arguably actionable under Consumer Fraud Act, then
 18 they can be -- then they can be sued on. That's precisely
 19 what has occurred here.

20 The allegations of this complaint show that
 21 through a variety of different methods, direct-to-consumer
 22 advertising and the sales force and the like, what
 23 AstraZeneca did has created the impression, either express by
 24 comparisons to Prilosec or implied by comparisons to Prilosec
 25 or through reinforcement ads, once they had been able to give

1 the impression that Nexium is better than Prilosec, the
2 continued and repeated drum beat throughout the country in
3 multi-media format that Nexium was better than Prilosec.

4 I will also point, your Honor, that there's
5 something of a little bit of a twist. We recognize that some
6 of the ads are not completely overt in stating that Nexium is
7 better than Prilosec. But as you know, one does not need
8 that for consumer protection claims. Implied superiority,
9 false and deceptive advertising, is capable of much more
10 broader constructions than the need to be able to parse the
11 text of a particular ad in order to be able to prove a claim
12 that is being made. That's, in fact, the fundamental purpose
13 of having consumer protection laws.

14 But I will say this: If AstraZeneca really
15 believed that the FDA had approved Nexium as better than
16 Prilosec, their ads would be singing that like a brass band,
17 and they don't because they know that the FDA didn't approve
18 it for that, and that's why their ads have to be far -- an
19 effort at being more subtle than making that complete overt
20 statement.

21 And this is not a point to be taken lightly.
22 If you're in a multi-billion dollar market and you're trying
23 to differentiate the new brand-name drug from the old
24 brand-name drug and you really believe that the FDA has said
25 it's superior, it makes no economic sense for a company like

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1 this not to be saying that in absolutely overt explicit
2 language in quotes to the FDA and the like. But they didn't
3 do that because they know, again, that's not what the FDA
4 did. The FDA actually did the opposite and that, therefore,
5 their game, Tom Scully's words, was going to be a bit more
6 subtle, and what they were going to do was make the
7 superiority claims, but do it in ways that don't end up
8 necessarily being overt.

9 Several times AstraZeneca has argued that you
10 have to look at the ads in the complaint. And I just want to
11 say that there are ads in the complaint, but there are also
12 examples. They're not all the ads, obviously, and there are
13 other allegations in the complaint that talk about and make
14 allegations regarding claims of superiority.

15 In addition, again, the case is not limited just
16 to the ads. It's also a broad-based promotional effort as
17 well that they had spent hundreds of millions of dollars on
18 as well.

19 So, again, I don't think it's appropriate just to
20 focus on the discrete number of ads.

21 So before I move away, then, from the preemption
22 argument, which sort of wraps up many of the points that I
23 was talking about here, this case does not attack the entire
24 practice of direct-to-consumer advertising for Nexium, though
25 it does attack AstraZeneca's effort through a broad-based

1 campaign to differentiate Nexium as better than Prilosec when
2 the evidence, signs and the FDA say it's not.

3 They say that, Well, our argument must be that it
4 never should have been brought to the market. That's not our
5 argument. You have to bring your product to the market
6 without making false and deceptive statements about it, and
7 here, AstraZeneca was in its own perception of a predicament
8 because it wanted to make billions of dollars on a product
9 that was not deserving of making a billion dollars on.

10 They say our case is, our view is that it was a
11 mistake for the FDA to have approved the product. That is
12 not our case at all. There's no allegation, there's no
13 suggestion at all that we think that the FDA made a mistake
14 in approving the product. The FDA can approve many, many
15 products and some of those products will be better than
16 preceding products that are on the market. Sometimes those
17 products will be as good as products in the market.
18 Sometimes those products may even be inferior to products
19 that are on the market.

20 The FDA's job is to look at the efficacy and
21 safety of the product, and if it satisfies that by placebo,
22 the product goes on the market.

23 There's nothing wrong with Nexium having been
24 approved. What's wrong here, again, what we said in the
25 complaint is having gotten it approved but having the

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1 superiority claim rejected, you can't go out and try to
2 differentiate your product as better. It's just not the
3 case.

4 And so this isn't a case where there's some kind
5 of effort to trample on commercial speech that has in some
6 way been sanctioned by the Federal Government. Quite the
7 contrary. It's the classic exercise of consumer fraud laws
8 to protect consumers from false and misleading advertising,
9 and really that's it.

10 THE COURT: And when you say that, we're talking
11 about consumers and we're kind of ignoring the filter of the
12 expert that stands between the drug company and the consumer,
13 the doctor who theoretically --

14 MR. SOBOL: No. I don't think it ignores the
15 doctor at all. In fact, it recognizes and the complaint
16 alleges that not only did AstraZeneca make its false and
17 deceptive statements to consumers, but it also made them to
18 doctors. And so -- and did it in quite an extraordinary way
19 because those 6,000 sales representatives aren't going out
20 and making representations to, you know, consumers. They're
21 going out and they're flooding doctors' offices, trying to
22 convince them to use Nexium.

23 And the other thing, too, by the way, is that,
24 when you have a learned intermediary, of course, you'd want
25 to have a learned intermediary, the primary purpose of the

1 learned intermediary's role is to protect the safety and
2 efficacy of the product. It's not necessarily to say that
3 Nexium is the same as Prilosec, so you should be taking
4 Prilosec because it might be cheaper.

5 There's no suggestion made by the plaintiffs, by
6 AstraZeneca in this case, that the role of doctors or that
7 the role that the learned intermediary doctrine plays is that
8 the learned intermediary is also protecting the pocketbooks
9 of the consumer or the consumer's insureds. And as a result,
10 and I think there are other issues that could be raised in
11 terms of the learned intermediary doctrine, too.

12 Some Courts, like the Perez court in New Jersey
13 indicated that, you know, if you have direct-to-consumer
14 advertising, the role of the learned intermediary doctrine is
15 eviscerated quite considerably because you now have the
16 manufacturer going directly to the consumer to try to
17 influence consumer choice and to try to influence consumer
18 dialogue with the doctor itself, too.

19 So for all of those reasons, probably the most
20 primary, of course, is that the allegations of the complaint
21 indicate that the false and deceptive advertising campaign is
22 itself being practiced directly on the doctors themselves,
23 learned learned intermediary doctrine wouldn't apply.

24 Turning, then, to the injury and causation
25 issues, the injury here is really, you know, it's a very

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1 quite simple injury. I'm going to give you another example
2 of a normal Consumer Protection Act case.

3 If I go into a store and I buy a carpet and I'm
4 lied to regarding the qualities of the product, the carpet
5 salesperson doesn't have as a defense, Well, you know, what
6 kind of carpet would you have bought, Mr. Sobol? Would you
7 have gone down the street and bought a fancier, you know,
8 carpet or a poorer product or something like that?

9 AstraZeneca's notion here that the allegations
10 must prove a hypothetical which is that which every
11 individual would otherwise have done in terms of which other
12 pill they would have purchased is irrelevant.

13 Here, the case is that each of the class members
14 that have made the allegations of this in this complaint have
15 alleged that they purchased a product and that they paid too
16 much for it or they wouldn't have bought it at all.

17 And it's a very classic situation where if you go
18 in and you are lied to or if there's a deceptive act or
19 practice that occurs, that there ends up being damage.

20 Now, here, it's even more persuasive because
21 here, this is Consumer Protection Act claim under the
22 Delaware Consumer Fraud Act. And one not need prove reliance
23 under the Delaware Consumer Fraud Act. So the notion about
24 whether or not one relied directly or not on this
25 representation is completely irrelevant under the law. What

1 the law simply requires is that we prove an intent to deceive
2 and the occurrence of an injury. We do not need to prove
3 reliance under the law. And there's an obvious connection
4 because why would somebody be buying a product that has been
5 costing more if there are other ways to get the same kind of
6 treatment elsewhere?

7 Now, we brief in our case the fact that under
8 Delaware law, there is no reason to be able to prove reliance
9 at all.

10 AstraZeneca relies heavily on a case, an
11 intermediate appellate court case out of New Jersey by the
12 name of -- well, in the Claritin case, but they ignore a more
13 recent New Jersey Supreme Court case that actually assists
14 with this. The more recent New Jersey Supreme Court case is
15 a case called Furst, F-u-r-s-t. I have the cite here. Just
16 a moment, your Honor.

17 (Pause.)

18 MR. SOBOL: In -- the first case citation, your
19 Honor, is 182 New Jersey 1, or 868 2nd, 435.

20 After the intermediate appellate court decision
21 in the Claritin case, the New Jersey Supreme Court case took
22 up a different case in which they discussed what it means to
23 have an ascertainable loss under the New Jersey Consumer
24 Fraud Act.

25 And there, and the reason I use this carpet

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1 notion, is this: What the New Jersey Supreme Court held is
2 that if you were to buy a carpet at \$100 that was really
3 worth \$200, could you have bought it for a hundred and it
4 ends up being worth \$10, you're entitled to your expectation
5 damages. You're entitled to the difference not between the
6 hundred dollars you spent and the \$10 it's worth, but between
7 the \$200 that the expectation was, the benefit of the bargain
8 was, of your purchase.

9 So you get the difference between \$200 and \$10
10 under the New Jersey Consumer Fraud Act. And the reason for
11 that, they said, was even if it seems like it might be some
12 kind of windfall, that even in a contract case you'd be able
13 to get your expectation damages.

14 So in a consumer fraud claim, by definition you
15 should be able to get at least what you get in a contract
16 action. They said the purpose is obviously also if the
17 Consumer Fraud Act are remedial and seek to be protective of
18 consumers. They said that's also the amount, by the way,
19 that one would treble under their Consumer Fraud Act. That's
20 what I would consider to be an expansive interpretation, but
21 an accurate one under the Consumer Fraud Act in New Jersey
22 post Claritin.

23 Here, this case is actually an easier case
24 because the expectation is that when consumers paid for
25 Nexium, they thought they were getting a product that was

1 worth that price, but they weren't. They were getting a
2 product that was worth, you know, generic Prilosec.

3 Here in this case, the bottom line ends up being
4 that the allegations of the complaint indicate that each of
5 the class representatives that are in this case allege that
6 they would not have purchased and would not have spent the
7 money if it had not been the wrongful conduct that had been
8 undertaken by AstraZeneca, and that's sufficient for the
9 Delaware Consumer Fraud Act. It's also sufficient for the
10 unjust enrichment claim.

11 Your Honor, finally, I want to turn your
12 attention on this causation issue and damage issue to what
13 really should be controlling precedent for this Court. Not
14 controlling, but obviously highly persuasive. It's the
15 decision at the Second Court of Appeals in Desiano on a case
16 that was merely identical. I'm trying to figure out what
17 page of my presentation this is.

18 If you can go, your Honor, first to Page 18, the
19 hand-out.

20 As you recall, your Honor, in the Coumadin case
21 that you sat on, while it was an antitrust case, the fact of
22 the matter was that an overcharge in the antitrust context
23 was sufficient for antitrust injury for consumers in that
24 matter. There were also consumer protection claims brought
25 in that case as well.

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1 What I would suggest, your Honor, is that here,
2 too, the overpayment for a drug that would not have been,
3 that overpayment would not have been made but for the
4 wrongful conduct of the defendant is sufficient injury for
5 the purposes of a consumer protection claim to be able to go
6 forward.

7 If you then turn to the next page, your
8 Honor, the Second Circuit in Desiano, there's actually
9 a typo there. It should be an O at the end of Desiano.
10 The opinion is really on all fours in terms of the causation
11 here.

12 Here, the Second Circuit was sitting on the
13 diabetes drug and they considered the hypothetical in
14 which a defendant drug company markets a new, but they
15 put that in quotes, much more expensive drug, claiming
16 that it is a great advancement when, in fact, the company
17 is simply replicating the Metamorphin formula and putting a
18 new label on it.

19 In other words, the only difference between
20 Metamorphin and the "new" drug is the new name and the higher
21 prescription price, paid almost entirely by the insurance
22 company. In that case, the "new" drug would be exactly as
23 safe and effective as Metamorphin, and thus would be -- there
24 could be no injury to any of the insurance companies'
25 insureds. Nevertheless -- no injury meaning no personal

1 injury. Nevertheless, the insureds' companies would be able
2 to claim precisely as they do here, that the defendant
3 engaged in a scheme to defraud it and that the company
4 suffered direct economic losses as a result.

5 So we suggest, your Honor, that this case,
6 which reversed a grant of a 12(b)(6) motion from the
7 underlying Court, quite clearly is not -- this indication is
8 the hypothetical that the Second Circuit was envisioning
9 there.

10 And then, finally, your Honor, if you go to
11 Page 20 of the complaint, there have been statements that
12 there isn't a sufficient allegation of causation, that kind
13 of thing.

14 Again, the complaint is quite, and it's
15 repeatedly throughout the complaint, we end up saying things
16 like, The foregoing advertisement was part of an unfair
17 scheme by AstraZeneca to falsely promote and create demand.
18 The next sentence, The effect of the unfair scheme was to
19 create demand for Nexium where no such demand would have
20 existed had they told the truth.

21 And then on page -- Paragraph 146 on Page 21,
22 The net effect of this misleading campaign was to establish
23 Nexium in the minds of doctors and consumers as a superior
24 drug for acid relief and as such, to allow it to command a
25 price substantially in excess of generic Prilosec. That and

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1 other allegations in the complaint indicate that there have
2 been sufficient allegations of causation.

3 One final observation, your Honor. In one of
4 your decisions, your Honor, in the Coumadin matter, dating
5 back to 1998, where there were 12(b)(6) proceedings involving
6 false and misleading allegations with respect to claims under
7 New York common law, but claims of New York common law that
8 are similar to the Consumer Protection Act claims that
9 are brought here under Delaware law, you wrote, at Page 55
10 to 56, "In the present case, the plaintiff alleges that due
11 to defendant's false and misleading statements, pharmacy
12 benefit managers, managed care companies and others refused
13 to purchase plaintiff's generic Coumadin. The facts reveal
14 that these entities normally preferred less expensive generic
15 drugs to branded pharmaceuticals. At this stage of the
16 proceedings, plaintiff is entitled to the inference that but
17 for defendant's false and misleading statements, these third
18 parties would have entered into contracts with plaintiff.
19 Plaintiff has presented sufficient factual support to state a
20 claim for relief under common law tortious interference, and
21 the motion to dismiss is denied."

22 I would argue, your Honor, that, similarly, here,
23 plaintiffs are entitled to the inference under the
24 allegations that we have alleged, under the Delaware Consumer
25 Fraud Act and under unjust enrichment that but for a

1 widespread, hundreds of millions of dollars spent, thousands
2 of sales representative, all making statements overtly or
3 subliminally or impliedly that Nexium was better than
4 Prilosec, It's the next purple pill, spend your money here,
5 it's going to be better, that under these facts and
6 circumstances, and given the allegations we have regarding
7 the increased sales for Nexium and the like, we're entitled
8 to the inference that but for that conduct, people would have
9 been buying a less expensive product, and, therefore, we're
10 entitled to go forward at this stage of the proceedings.

11 Thank you.

12 THE COURT: All right. Thank you.

13 MR. HADDAD: Your Honor, thank you very much for
14 your time and patience this morning. If I may just respond
15 to a few of the points, I would greatly appreciate it.

16 I'd like to begin where Mr. Sobol began because I
17 think that his first point really is a good illustration of
18 our fundamental point.

19 Mr. Sobol began by directing the Court's
20 attention to Pages 7 and 8 of his handout, and Pages 7 and 8
21 of his handout contain excerpts of several paragraphs of his
22 complaint. And these excerpts are alleged to be portions of
23 an FDA medical reviewer report that accompanied the agency
24 action that was part of the agency's decision.

25 As the Court will recall, our basic theme

1 is that what plaintiffs are doing here is attacking agency
2 action, and there is perhaps no more stark evidence of this
3 than plaintiffs' selective use of this medical review or
4 report.

5 I just want to note two things about it: First,
6 Pages 7 and 8 of selected excerpts stop after Paragraph 76 of
7 the complaint. They don't go on to include Paragraph 79.
8 Paragraph 79 of the complaint is perhaps in hindsight a
9 paragraph plaintiffs wish they did not plead, but in that
10 paragraph, plaintiffs allege that the same FDA medical
11 reviewer recommended a dosage of Nexium of 20 milligrams once
12 a day because this medical reviewer saw, as plaintiffs allege
13 it, no benefit increasing the dose from 20 to 40.

14 Now, as the Court can tell from the labeling,
15 which is the final agency action, the labeling approves a
16 40-milligram dose. The labeling is the final agency action.
17 That's what sets the parameters for the scope of
18 advertising. That is the basis, and plaintiffs, I don't hear
19 them challenging this as a legal matter, that tests the
20 framework and the basis for what is permissible as a matter
21 of federal law for AstraZeneca to say.

22 And we've cited to the Court the Pfizer v. Miles
23 case, where the District Court there similarly rejected a
24 party's attempt to argue on the basis of an accompanying
25 report that was inconsistent with the final agency action.

2 complexity and the details that plaintiffs have included in
3 their complaint. Our position is a simple one: That the
4 labeling sets the framework, and this morning I think we've
5 heard Mr. Sobol and the plaintiffs make some important
6 concessions.

7 Mr. Sobol has essentially, as I heard it, given
8 up on the omission theory that is throughout this complaint.
9 You did not hear him argue that AstraZeneca can be faulted
10 for omitting to tell patients and others in their ads that
11 Prilosec is the exact same as Nexium. As I heard it, that
12 complaint, that argument is abandoned.

13 We also heard Mr. Sobol say that it's very
14 telling that there's no brass band, I think was his phrase,
15 of music playing the theme that or stating that, trumpeting,
16 I think, that Nexium is better than Prilosec.

17 And not only is there not a brass band, but
18 there's not a sentence. He has pointed, and his complaint,
19 plaintiffs' complaint has pointed to not one single sentence
20 anywhere in these ads that says that Nexium is better than
21 Prilosec. It's not there to be found. They have attached a
22 dozen print ads. They've quoted from four different
23 television advertisements.

24 He says, Well, this is not the universe. Well,
25 okay, it's not the universe, but they've had several times to

1 plead this case. They cannot find a single ad that contains
2 the comparative statement that they say we can't make.

3 The thrust of Mr. Sobol's presentation this
4 morning was that the FDA did not say on the labeling that
5 Nexium is better than Prilosec. Well, that's fine.
6 AstraZeneca doesn't say in the ads that Nexium is
7 better than Prilosec.

8 What plaintiffs want to litigate instead are
9 implications, and if the Court would look, for example, at
10 Paragraph 120 and 121, that is where plaintiffs in their
11 complaint summarize what they think is wrong with the
12 television ads. And I think it's illustrative to see how
13 empty plaintiffs' claims that AstraZeneca could have
14 advertised Nexium properly are.

15 Plaintiffs say that these are the key themes and
16 phrases, this is their words, in television advertisements
17 during the class period. These are the claims that they say
18 are misleading. "Talk to your doctor about Nexium. One
19 prescription daily, heartburn goes away and stays away.
20 Heals erosion in esophagus. Across America, doctors who
21 specialize in acid reflux disease have switched more patients
22 to Nexium than any other prescription of its kind. For many,
23 24-hour heartburn relief."

24 These are the themes that they say are the key
25 themes. I've just read all of them from Paragraph 120.

1 They claim that these are all deceptive
2 statements. Our position is if we cannot make these
3 statements, if we cannot say that Nexium is new, even though
4 the FTC and the FDA expressly have guidance that permit the
5 use of the word "new" in advertising for the first six months
6 after a product is approved as new, if we cannot make the
7 statements that we did make, how are we supposed to advertise
8 this product at all?

9 They have come into court with a frontal assault
10 on everything that AstraZeneca said, whether it referred to
11 Prilosec or not. They have not attacked, because they have
12 not found a single offending comparative statement. That is
13 not a basis for a federal lawsuit.

14 I would just briefly like to address two points
15 where I think there was some confusion in the causation
16 area.

17 One, the Court will be most familiar
18 with the Coumadin case, and briefly, our position is that
19 is a fundamentally different factual situation than the
20 one here.

21 In the Coumadin case, there was one branded
22 product being challenged by one generic competitor. And the
23 manufacturer of the branded product directly attacked the
24 generic as not being equivalent to its product.

25 And so in that antitrust context, where the one

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1 manufacturer had a monopoly and was directly attacking the
2 one potential competitor, there were allegations sufficient
3 to support an inference of causation.

4 We don't have that remotely in this case. We
5 have no allegation of monopolies. We have multiple products
6 in the same space. We have no ability for an inference about
7 what the alternative would be. There are half a dozen
8 products, at least, in this market. So Coumadin is not
9 helpful.

10 The other case that plaintiff drew the Court's
11 attention to this morning was Desiano, and that is remarkable
12 and deserves a brief mention here.

13 Desiano is a Second Circuit decision, Judge
14 Calabrese for the Panel, and it's about causation. It's a
15 case where third-party payers alleged that they wouldn't have
16 put Rezulin on their formularies if they had known about the
17 safety risks that they alleged the manufacturer disguised.

18 The manufacturer said, Well, third-party payers
19 don't have standing because they didn't suffer the adverse
20 health effects of this product that is allegedly unsafe, so
21 they don't have standing.

22 Judge Calabrese, writing for the Panel, said,
23 Wait, hold on a minute. They paid more for this drug than
24 they would have, so they suffered an economic injury even
25 though they weren't physically harmed, so they have standing

to raise this case, this claim.

2 Two things, then, follow from this.

3 First, in explaining why the third-party payers
4 would have standing, Judge Calabrese used a hypothetical.

5 That when the Court reviews this case, as I urge
6 the Court to do, the Court will see the hypothetical is
7 designed to take away the issue of physical injury and create
8 a pure economic loss fact pattern. And then he says, This
9 fact pattern shows that they would have an economic loss, so
10 economic loss is enough.

11 What he does not address is whether that fact
12 pattern would create a viable claim for preemption purposes.
13 The word "preemption" isn't in that case. The issue is not
14 addressed. And his hypothetical fact pattern would be a fact
15 pattern that would be squarely preempted by the Buckman case
16 because it's a fact pattern about fraud on the FDA. It's a
17 hypothetical for a different purpose.

18 Secondly, if the Court looks at, I believe it's
19 Footnote 9 of Desiano, the Court will see the kinds of
20 allegations that the third-party payers made in that Rezulin
21 litigation that were relevant to causation. Those are
22 precisely the kind of allegations that are entirely absent
23 from the complaint in this case.

24 Unless the Court has further questions...

25 THE COURT: No. Thank you very much.

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1 MR. HADDAD: Thank you, your Honor.

2 MR. SOBOL: May I have just a moment, your
3 Honor?

4 THE COURT: You may.

5 MR. SOBOL: First, your Honor, with respect to
6 the argument that somehow approval of a 40-milligram dosage
7 of Nexium in some way means that there's a superiority claim
8 in the implicit or somewhere underlying in the FDA approval,
9 again, that's the kind of leap of faith that AstraZeneca
10 would want one to make from a record, but completely contrary
11 to the allegations in the complaint.

12 There would be a variety of reasons why it
13 is the FDA might think that a 40-miligram dosage of Nexium,
14 which has absent a certain isomer that is present in
15 Prilosec, might be necessary for it to be more effective than
16 a placebo. A variety of other reasons, but it does not mean
17 that one then jumps the gun and think that the FDA did a
18 complete turnaround of what the conclusions are that are made
19 in the underlying record and their rejection of the claim
20 being made by the sponsor, the absence on the label of the
21 claim that was made by the sponsor of superiority. If
22 anything, again, the conclusion that is made on the basis of
23 these allegations is that it's the exact opposite.

24 Second, I honestly don't know whether we've given
25 up or still adopt the omission theory because I don't know

1 what the defendants mean by the omission theory.
 2 This case is based upon affirmative statements
 3 of fact and failures to state things because they're
 4 their voluntary business decision to go into the
 5 marketplace for the broad-based campaign of superiority
 6 put them in a situation where they were making claims and
 7 telling half truths or full truths, and that's what the
 8 case is about.

9 And so I don't know, you know, this notion
 10 that we are not required to say, you know, the word, the
 11 additional words that you should have been saying in order to
 12 correct things. We're saying that what you did, that what
 13 you said is wrong, was a false and deceptive act under the
 14 Delaware Consumer Protection Act, and that's enough.

15 The allegations of the complaint do have and
 16 do contain express comparative statements. We point to the
 17 fact that even in AstraZeneca's 2000 annual report, when
 18 they're launching the Nexium effort, they say that Nexium is
 19 the, on Page 2 of my slides, your Honor, Nexium is the first
 20 PPI to offer significant clinical improvements over Losec,
 21 that's the British brand name, in terms of acid control,
 22 clinical efficacy. They're saying that it was shown in
 23 studies involving 30,000 people performed in 20 countries
 24 across the world, that it's expected to establish a new,
 25 improved treatment standard in the PPI class and that Nexium

1 is more effective.

2 These are statements being made by AstraZeneca,
 3 quite clearly evidencing the corporate decision that there
 4 is going to be a superiority and that the effort that --
 5 the overall business objectives of this company going
 6 forward and the expenditure of hundreds of millions of
 7 dollars are going to be improving that as the basis to
 8 do the differentiation.

9 The next slide, your Honor, at Page 3, I, again,
 10 I point to allegations in the complaint, not just to parsing
 11 those specific advertisements that obviously have gone
 12 through the legal, you know, review at AstraZeneca, but also
 13 looking at the massive detailing efforts that were undertaken
 14 and the representations that were being made to doctors as to
 15 why Nexium was better.

16 So there are some of express efforts made to you
 17 about distinctions between Nexium and Prilosec. And, again,
 18 to the extent that the comparisons are implicit, then they
 19 are precisely the fodder of a Consumer Protection Act. It is
 20 not the case that we let a company deceive consumers, deceive
 21 doctors based upon, you know, a campaign that they know is
 22 intended to make claims of superiority. You really can't
 23 find those words in it. It's just not the case in the
 24 consumer protection law.

25 And there's also a common sense approach here,

1 your Honor. If you look at these ads, and we know just
 2 what's out there in the marketplace, who's kidding who? Of
 3 course, the overall business objectives were to position
 4 Nexium as a brand better than Prilosec. That was their whole
 5 mission: Brand positioning. And what they tried to do was
 6 brand position Nexium as better than Prilosec contrary to the
 7 science, contrary to the evidence, contrary to the FDA. And
 8 that's what's going on here. And it is not appropriate on a
 9 12(b)(6) motion to try to have a Court so narrowly construe a
 10 Consumer Protection Act as to defy common sense. That's what
 11 the Consumer Protection Act is.

12 Who's kidding who? Common sense. You know what
 13 they were doing here. That's what the allegations had. We
 14 should be able to proceed forward and be tested on the
 15 evidence at summary judgment.

16 Thank you.

17 THE COURT: Is the claim of superiority that
 18 you are claiming, the alleged claim of superiority matter,
 19 maybe that's the best way of saying it, the dosage, the
 20 40 milligrams approved over the 20, or is it the actual
 21 drug?

22 MR. SOBOL: The way this advertising campaign
 23 went forward is: Nexium is better than Prilosec, spend your
 24 money on Nexium.

25 This is not a double-dose case. We do not have

1 to show that they should have been doing anything else. What
 2 we are saying is what they did, in fact, was false and
 3 misleading. Nexium is better than Prilosec. And that's not
 4 true. And the FDA has said it and Tom Scully said it and our
 5 allegations allege it.

6 THE COURT: All right. Thank you.

7 MR. SOBOL: Thank you.

8 THE COURT: Since it is the defendants' motion, I
 9 will always give them the last word.

10 Anything further?

11 MR. HADDAD: I appreciate your Honor's generosity
 12 and I will just make one final point.

13 The plaintiffs' complaint concedes several places
 14 that the studies that were submitted to the FDA included
 15 studies that showed that Nexium was better than Prilosec,
 16 more effective at treating erosive esophagitis. Just one
 17 example is Paragraph 58, but they're all cited in the
 18 complaint, in our briefs.

19 So it's not fair, I think, to say that the theory
 20 of the complaint is that there's no difference between these
 21 two compounds. It's there in the complaint. The FDA did
 22 approve precisely what the plaintiffs say is a game, a higher
 23 dose of Nexium that shows more effectiveness at healing
 24 erosive esophagitis. That is what the FDA did, and
 25 plaintiffs want to litigate something that they feel is in

1 the air, that everybody knows that a new drug was positioned
2 as better than an old drug.

3 But when the FDA approves a new drug, approves it
4 based on studies that support a higher dosage because they
5 were shown to be more effective at healing, a company is
6 clearly permitted under federal law to announce that new
7 drug, be proud of it, say that it's new, say that it's
8 powerful, say that it heals the indications for which it is
9 approved to heal, encourage patients to talk to their doctor
10 about it. That is what the law permits. That is what the
11 First Amendment permits. And absent some specific
12 comparative statement or other factual statement in an ad to
13 which this complaint has failed entirely to point that could
14 be said to be outside the scope of the label, there's simply
15 nothing to litigate.

16 THE COURT: In the last comments, plaintiffs'
17 counsel wasn't pointing to ads, they were pointing to public
18 disclosures as in the SEC statement. How does that fall into
19 the scheme of things?

20 MR. HADDAD: Your Honor, they've pointed to one
21 statement in an annual report from the year 2000, prior to
22 the launch of Nexium, which I believe is described in the
23 complaint as launching in 2001. But, in all events, it was a
24 statement in an annual report. There's no allegation that
25 any plaintiff or anybody saw this annual report. Their point

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1 is, Well, this shows the company's attitude towards its
2 product, but the annual report predates the FDA approval
3 and the launch materials and the introduction of the product,
4 and what they really need to litigate if they want to
5 litigate something, our position is they have to litigate
6 the ads.

7 They have decided we've discussed this in the
8 briefs, and they have not cited any authority that says you
9 can attack an entire DTC advertising campaign because of
10 something you said in an annual report prior to the
11 campaign.

12 THE COURT: All right. Thank you very much,
13 counsel. We'll do our best to get something out to you
14 promptly.

15 (Counsel respond, "Thank you, your Honor.")

16 (Court recessed at 11:35 a.m.)

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